K111189

DEC 2 0 2012

510(k) SUMMARY

The summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

Submitter's name :	Syntec Scientific Corporation
Address :	2, Kung San Rd, Chuan Shing Industrial Zone, Shen Kang, Chang Hua, Taiwan Tel : 886-4-7987099 Fax: 886-4-7987077
Date :	December 17, 2012
Contact person :	Chia-Ching Lee
Name of the device :	Syntec Dental Implant
Trade or proprietary name :	Syntec Dental Implant
Common name:	Dental implant, Dental implant abutments
Classification name :	Endosseous dental implant, Endosseous dental implant abutments
Produce Code :	DZE, NHA
Regulation Number :	872.3640, 872.3630
Class :	II
Predicate device:	Dentium Company Limited Implantium, K041368 Implantium Prosthetics, K052957

Description of the Device:

The Syntec Dental Implant provides Titanium Alloy (commercially followed by ASTM F136) intended to be surgically placed in the bone of the upper or lower jaw arches. To provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It consists of implant, cover screw, healing abutment, abutment screw and abutments. The Syntec Dental Implant is for one and two stage surgical procedures. Its materials, dimensions, and intended use are similar to devices currently marked worldwide. The range of implant in diameter is from 3.4mm to 4.8mm and in length from 8.0mm to 14.0mm. The range of abutment in diameter is from 4.5mm to 6.5mm, and in length from 5.5mm to 12.0mm.

Indications for Use:

The Syntec Dental Implant is intended to be surgically placed in the bone of the upper or lower jaw arches. To provide support for prosthetic devices, such as to restore the patient's chewing function, and artificial teeth. It is intended for delayed loading.

Device Comparison Table

	Predicate Device	Applicant
Sponsor	Dentium Co., Ltd.	Syntec Scientific Corporation
Device name	Dentium Company Limited Implantium Implantium Prosthetics	Syntec Dental Implant
510(k) number	K041368 K052957	K111189
Similarities:		
Regulation number/ name/ class/ product code	Class II §872.3640, 872.3630/ Endosseous dental implant, Endosseous dental implant abutment/ DZE, NHA	Class II §872.3640, 872.3630/ Endosseous dental implant, Endosseous dental implant abutment/ DZE, NHA
Intended for Use	The Dentium Co., Ltd Implantium is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. Implantium prosthetics is intended for use as an aid in prosthetic rehabilitation.	The Syntec Dental Implant is intended to be surgically placed in the bone of the upper or lower jaw arches. To provide support for prosthetic devices, such as to restore the patient's chewing function, and artificial teeth. It is intended for delayed loading.
Diameters of Implant	From 3.4mm to 4.8mm	From 3.4mm to 4.8mm
Lengths of Implant	From 8.0mm to 14.0mm	From 8.0mm to 14.0mm
Diameters of Abutment	From 4.0mm to 6.5mm	From 4.5mm to 6.5mm
Lengths of Abutment	From 5.5mm to 12.0mm	From 5.5mm to 12.0mm
Single Use?	Yes	Yes
Mechanical Properties	Good	Good
Differences:		
Materials	Pure titanium and titanium alloy	Titanium alloy
Sterility	Sterile	Implant and cover screw are sterile. Other components are non-sterile.

Bench Testing:

Overview all bench Testing:

Testing Item	Standard and regulations applied	Submitted on
Biomechanical testing		
Static strength	ISO 14801	November 25, 2011
Fatigue testing	ISO 14801	November 25, 2011
Biocompatibility		
Certificate of Raw material	ISO-10993	April 26, 2011
Sterilization：		
Sterilization Validation of Gamma Irradiation	ISO 11137	November 25, 2011
Sterilization Validation of Moist Heat Sterilization Process Validation	ISO 17665-1, ISO 17665-2, ISO 11737-1 and ISO 11737-2	November 09, 2012
surface analysis		
Morphology	SEM	August 7, 2012
Coating thickness	EN ISO 4288	August 7, 2012
Ca/P ratio	EN ISO 11885-E22	August 7, 2012
Residue analysis	ASTM F1854/ DIN EN ISO 4288	August 7, 2012
Cytotoxicity	DIN EN ISO 10993-5	August 7, 2012
Solubility	FDA guidance (2/21/97)	August 7, 2012
Analysis of raw material	ASTM F1185 and ASTM F1609	August 7, 2012
Adhesive Tensile Strength	ASTM F-1147	November 09, 2012
Shear Strength	ASTM F-1044	November 09, 2012

Brief discussion of Biomechanical Studies: The experiments were according ISO 14801 (Dentistry – Implant – Dynamic Fatigue Test for Endosseous Dental Implants). In these experiments, the static strength and fatigue life were evaluated. The result of Dental Implant is substantially equivalent to predicate devices.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Syntec concludes that Dental Implant is substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2012

Ms. Chia-Ching Lee
Regulatory Affairs Specialist
Syntec Scientific Corporation
2, Kung San Road
Chuan Shing Industrial Zone
Shen Kang, Chang Hua
Taiwan

Re: K111189
Trade/Device Name: Syntec Dental Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 17, 2012
Received: December 19, 2012

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

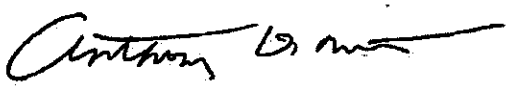
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

Indications for Use

510(k) Number (if known): k111189
Device Name: Syntec Dental Implant
Indications for Use:
The Syntec Dental Implant is intended to be surgically placed in the bone of the upper or lower jaw arches. To provide support for prosthetic devices, such as to restore the patient's chewing function, and artificial teeth.

Prescription Use _____X_____ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.12.20 13:32:08 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: k111189